

M. Grievances, Organization Determinations, and Appeals(Subpart M)

1. Background and General Provisions (§§422.560 through 422.562)

Subpart M of part 422 implements sections 1852(f) and (g) of the Act, which set forth the procedures M+C organizations must follow with regard to grievances, organization determinations, and reconsiderations and other appeals. Under section 1852(f) of the Act, an M+C organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any other entity or individual through which the organization provides health care services) and enrollees in its M+C plans. Section 1852(g) of the Act addresses the procedural requirements concerning coverage ("organization") determinations and reconsiderations and other appeals. Only disputes concerning "organization determinations" are subject to the reconsideration and other appeal requirements under section 1852(g). In general, organization determinations involve whether an enrollee is entitled to receive a health service or the amount the enrollee is expected to pay for that service. All other disputes are subject to the grievance requirements under section 1852(f) of the Act. For purposes of this regulation, a reconsideration consists of a review of an adverse organization determination (a decision that is unfavorable to the M+C enrollee, in whole or in

part) by either the M+C organization itself or an independent review entity. We use the term "appeal" to denote any of the procedures that deal with the review of organization determinations, including reconsiderations, hearings before administrative law judges (ALJs), reviews by the Departmental Appeals Board (DAB) and judicial review.

For the grievance, organization determination, and appeal requirements, an M+C organization must establish procedures that satisfy these requirements with respect to each M+C plan that it offers. These requirements generally are the same for each type of M+C plan-including M+C non-network MSA plans and M+C PFFS plans. (Please refer to the preamble material on M+C appeals and grievances in the June 26, 1998 interim final rule (63 FR 35021) for a detailed discussion of the specific requirements under Subpart M.)

Additional regulatory improvements to the M+C appeal and grievance processes are currently under development. We included in the M+C interim final rule those improvements that were practical within the short time frame allotted for completing that interim final rule. As we indicated in the preamble to the M+C interim final rule (63 FR 35030), we intend in the near future to publish a proposed rule implementing a variety of other improvements to the M+C dispute resolution process, including both appeals and grievances.

Sections 422.560 and 422.561 contain the basis and scope and the relevant definitions for subpart M. Section 422.562, General Provisions, provides an overview of the rights and responsibilities of M+C organizations and M+C enrollees with respect to grievances, organization determinations, and appeals. The responsibilities of M+C organizations, under §422.562(a), essentially parallel those applicable to HMOs under §417.604(a), with the added provision that, if an M+C organization delegates any of its responsibilities under subpart M to another entity or individual through which the organization provides health care services, the M+C organization is ultimately responsible for ensuring that the applicable grievance and appeal requirements are still met.

Section 422.562(b) explains the basic rights of M+C enrollees under subpart M, and provides regulatory references to the sections that fully explain the relevant rights. This section does not establish any rights beyond those previously provided for HMO enrollees under part 417, but consolidates general information about enrollees' rights into a central location in the regulations.

Like the part 417 regulations, §422.562(b) contains provisions addressing the applicability of other regulations that implement Social Security appeals procedures under title II of the Act.

2. Grievance Procedures (§422.564)

Section 1852(f) of the Act requires that each M+C organization provide "meaningful procedures for hearing and resolving grievances." We have defined this term in §422.561 as any complaint or dispute other than one that involves an "organization determination" (as described under §422.566(b)). (This definition retains the meaning of grievance used in part 417.) An enrollee might file a grievance if, for example, the enrollee received a service but believed that the demeanor of the person providing the service was insulting or otherwise inappropriate. Also, as specified under §§422.570(d)(2)(ii) and 422.584(d)(2)(ii), grievance procedures would apply when an enrollee disagrees with an M+C organization's decision not to grant an enrollee's request to expedite an organization determination or a reconsideration.

Under §422.564(a), an M+C organization must resolve grievances in a timely manner using procedures that comply with any guidelines which we establish. Section 422.564(c) clarifies that the PRO complaint process under section 1154(a)(14) of the Act addresses quality issues, but is separate and distinct from the M+C organization's grievance procedures. Thus, there are three different complaint processes (grievance, appeals and PRO processes) available to an enrollee in an M+C organization.

3. Organization Determinations (§§422.566 through 422.576)

Section 1852(g) of the Act requires an M+C organization to establish procedures for hearing and resolving disputes between the organization and its Medicare enrollees concerning organization determinations. In accordance with section 1852(g)(1) of the Act, §422.566 specifies that an M+C organization must have a procedure for making timely organization determinations regarding the benefits an enrollee is entitled to receive and the amount, if any, that an enrollee must pay for a health service. Also, an M+C organization's refusal to provide services that the enrollee believes should be furnished or arranged for by the M+C organization is an action that constitutes an organization determination. Disputes involving additional benefits, as well as mandatory and optional supplemental benefits, also constitute organization determinations and are subject to the appeals process.

Section 422.566(b) lists actions that are organization determinations, and with two exceptions, follows the previous HMO regulation at §417.606(a). The exceptions involve the inclusion as organization determinations of decisions involving--(1) optional supplemental benefits, and (2) payment for post-stabilization services.

Section 422.568 includes the standard time frame and notice requirements for organization determinations. Under §422.568(a),

an M+C organization must make a determination with respect to an enrollee's request for service as expeditiously as the enrollee's health status requires, and in no case later than 14 calendar days after the organization receives the request. An M+C organization may extend the time frame by up to 14 calendar days if the enrollee requests the extension, or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee; (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). The M+C organization must include a written justification for the extension in the case file.

Section 422.568(b) specifies that time frames for requests for organization determinations on payment issues are identical to the "prompt payment" requirements set forth under §422.520. Thus, for issues relating to payment, the requirements are as follows: (1) For "clean claims," an M+C organization must make a determination regarding the claim within our current "clean claim" rules, that is, 95 percent of clean claims must be paid within 30 calendar days after receipt of the request for payment; (2) for all other claims, an M+C organization must make a determination regarding the claim within 60 calendar days after receipt of the request for payment. (Under existing §422.500, "clean claims" are claims that have no defect, impropriety, lack

of any required substantiating documentation, or particular circumstances requiring special treatment that prevents timely payment. See section II.K of this preamble for a further discussion of rules regarding clean claims and prompt payment.)

Consistent with section 1852(g)(1)(B) of the Act, §422.568(c) and (d) require that an M+C organization issue written notification for all denials of a request for services, including the specific reasons for the denial in understandable language, information regarding the enrollee's right to either an expedited or standard reconsideration, and a description of both the expedited and standard review processes, as well as the rest of the appeals process.

Sections 422.570 and 422.572 set forth the requirements for M+C organizations with respect to expedited determinations. Sections 422.570(a) (for expedited organization determinations) and 422.584(a) (for expedited reconsiderations) allow either an enrollee or a physician to request an expedited organization determination or reconsideration, regardless of whether the physician is affiliated with the M+C organization. Under §422.570(a), any physician can request an expedited organization determination. Section 422.584(a) provides that a physician who requests an expedited reconsideration must be acting on behalf of the enrollee as an authorized representative.

Section 422.570(b)(2) specifies that a physician may provide written or oral support for a request for expedition, and under §422.570(c)(2)(ii), requests for expedited organization determinations that are made or supported by a physician must be granted by the M+C organization if the physician indicates that the enrollee's health could be jeopardized.

Under §422.568(d)(1), an M+C organization must automatically transfer a denied request for an expedited organization determination to the standard 14-day time frame described in §422.568(a), and §422.570(d)(2)(ii) requires an M+C organization to inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision not to expedite. We also require under §422.570(c)(1) that an organization establish an efficient and convenient means for individuals to submit oral or written requests for expedited organization determinations and document any oral requests. We clarify under §422.570(b)(1) that procedures may involve submitting a request to another entity responsible for making the determination, as "directed by the M+C organization."

Section 422.572(a) requires an M+C organization to notify the enrollee (and the physician involved, as appropriate) of an expedited determination as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request. Under §422.572(b), an M+C organization may extend the

72-hour deadline for expedited review by up to 14 calendar days if the enrollee requests the extension or if the organization finds that additional information is needed and the delay is in the interest of the enrollee. Also under this section, an M+C organization must notify an enrollee of a determination as expeditiously as the enrollee's health care needs require but no later than upon expiration of the extension.

Provisions in both §§422.570(f) and 422.584(f) prohibit an M+C organization from taking or threatening to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited organization determination or reconsideration.

Section 422.574 identifies the parties to an organization determination, which include the enrollee, certain physicians and other providers who are assignees of the enrollee, legal representatives of a deceased enrollee's estate, and any other entity (other than the M+C organization) determined to have an appealable interest in the proceeding.

4. Reconsiderations by an M+C Organization or an Independent Review Entity (§§422.578 through 422.616)

If a decision regarding a request for payment or service is unfavorable (in whole or in part) to the enrollee, the enrollee or any other party to an organization determination as listed in §422.574 who is dissatisfied with the organization determination

may request that the M+C organization reconsider the decision. Reconsiderations represent the first step in the appeals process. The reconsideration process encompasses both standard and expedited reconsiderations, as described under §§422.582 and 422.584. The time frame and notice requirements for reconsiderations are set forth under §422.590.

Section 422.590(a)(1) requires that, with respect to standard reconsiderations concerning requests for service, an M+C organization must issue any determination that is entirely favorable to the enrollee as expeditiously as the enrollee's health condition requires but no later than 30 calendar days after it receives the request for reconsideration. As with organization determinations, §422.590(a) also provides that the M+C organization may extend the time frame by up to 14 calendar days if the enrollee requests the extension, or if the organization justifies a need for additional information, and how the delay is in the interest of the enrollee. Under §422.590(b)(1), for standard reconsiderations involving requests for payment, the M+C organization must issue any fully favorable determination no later than 60 calendar days from the date it receives the request for the reconsideration.

In the case of expedited reconsiderations (which involve only requests for services), §422.590(d)(1) requires that an M+C organization issue any determination that is entirely favorable

to the enrollee as expeditiously as the enrollee's health condition requires but no later than 72 hours after it receives the request for expedited reconsideration, again with the possibility of a 14-day extension as described in §422.590(d)(2). If, however, the M+C organization's reconsideration results in an affirmation, in whole or in part, of its original adverse organization determination, this decision is automatically subject to further review by an independent entity contracted by us. (Again, the time frame within which an M+C organization must reconsider a standard or expedited case has been tied to the enrollee's health needs for service requests, subject to either a 30-day or 72-hour maximum (with a possible 14-day extension), while the time frame remains at 60 days for reconsideration requests involving payment.)

Section 1852(g)(4) of the Act requires us to contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm, in whole or in part, an M+C organization's denial of coverage. Thus, unless an M+C organization completely reverses its coverage denial, it must prepare a written explanation, and refer the case to the independent review entity for a new and impartial determination concerning the payment or service at issue.

Section 422.590(a)(2) provides that for standard requests for services, an M+C organization that makes a reconsidered

determination affirming, in whole or in part, its adverse organization determination, must send the case file to the independent review entity as expeditiously as the enrollee's health requires, but no later than 30 calendar days from the date the M+C organization receives the request for a standard reconsideration (or the date of an expiration of an extension). For standard requests for payment, §422.590(b)(2) allows the M+C organization 60 calendar days from the date it receives the request to send the case to the independent review entity. In instances involving expedited requests for reconsideration, §422.590(d)(5) requires that the M+C organization forward its decision to the independent entity as expeditiously as the enrollee's health condition requires, but not later than within 24 hours of its affirmation of the adverse expedited organization determination.

Section 422.590(g)(2) requires that any reconsideration that relates to a determination to deny coverage based on a lack of medical necessity must be made only by a physician with expertise in the field of medicine that is appropriate for the services at issue.

For the most part, the procedures outlined above were carried over into the M+C requirements from the existing part 417 standards. We also implemented several changes in the reconsideration requirements that are analogous to those

described for organization determinations, such as the requirement under §422.584(d)(1) that an M+C organization automatically transfer a denied request for an expedited reconsideration to the standard 30-day time frame described in §422.590(a). In addition, §422.590(e) requires that if an M+C organization refers a case to the independent entity, it must concurrently notify the enrollee of that action.

Consistent with section 1852(g)(4) of the Act, §§422.592 and 422.594 address reconsiderations by an independent entity. If the independent review entity's reconsidered determination is not fully favorable to the enrollee, subsequent review possibilities include ALJ and Departmental Appeals Board (DAB) hearings, as well as judicial review. Provisions addressing these forms of review are set forth in §§422.600 through 422.616.

5. Effectuation of a Reconsidered Determination (§422.618)

Section 422.618 established effectuation requirements for payments and services. For reconsiderations of requests for payment, when an M+C organization reverses its adverse organization determination, it must pay for the service no later than 60 calendar days after the date that the M+C organization receives the request for reconsideration. For reconsiderations of requests for service, when an M+C organization reverses its adverse organization determination, it must authorize or provide the service under dispute as expeditiously as the enrollee's

health condition requires, but no later than 30 calendar days after the M+C organization receives the request for reconsideration, or no later than upon expiration of a 14 calendar day extension. When the M+C organization is reversed by the independent review entity or higher review level, the M+C organization must pay for, authorize, or provide the service as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date the M+C organization receives notice reversing its organization determination.

6. Notification of Noncoverage in Inpatient Hospital Settings (§§422.620 and 422.622)

Sections 422.620 and 422.622 pertain to M+C organizations' responsibilities in connection with inpatient hospital care. The existing provisions clarify that inpatient services continue to be covered only until written notice of noncoverage in situations in which the hospital admission was authorized in the first instance by the M+C organization, or in which the admission constituted urgent or emergent care. This notice now is issued to enrollees by the M+C organization, either directly or through the hospital, with the concurrence of the attending physician responsible for the enrollee's hospital care. Section 422.622 provides enrollees with the right to seek PRO review by noon on the day after the receipt of the notice if the enrollee believes that he or she is being discharged too soon. The enrollee bears

no additional financial liability for care furnished during the period of PRO review, regardless of the proposed date of discharge. If the enrollee misses the noon deadline for requesting PRO review, the enrollee may file an expedited appeal with the M+C organization. Unlike the PRO review process, there is no financial protection afforded to the beneficiary while the M+C organization conducts its review.

Subpart M Comments and Responses

7. Definitions and General Provisions

Comment: One commenter suggested that the definition of appeal should read as follows: "Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care or health care services an enrollee is entitled to receive, including delay in providing or approving the health care or health care services...."

Response: We generally agree with the commenter and are revising the definition in §422.561 to incorporate most of the commenter's suggested language. We are omitting "health care" as we believe the language duplicates and is inferred in the meaning of "health care services." We are adding the term "arranging for" to the definition. Therefore, we are adopting the following revision to the appeals definition: "Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care services the enrollee believes

he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service, as defined under §422.566(b). These procedures include reconsiderations by the M+C organization, and if necessary, an independent review entity, hearings before ALJs, review by the Departmental Appeals Board (DAB), and judicial review."

8. Grievances (§§422.564, 422.570, and 422.584)

Comment: Two commenters contended that we should not establish prescriptive grievance procedures, while several supported establishing standards. One commenter stressed that any grievance requirements we imposed should be consistent with those applied by accrediting organizations, so that M+C organizations would not have to change current procedures to a great extent. The commenter expressed concern about State privacy requirements, as M+C organizations currently are prevented under State law in some cases from providing specific information on how grievances have been resolved. Rather, in these cases, organizations are only allowed under State law to inform enrollees that the complaint has entered the tracking system. One commenter stated that grievance procedures should be flexible, given our interpretation of preemption provisions. One commenter strongly encouraged establishing mandatory time frames

for the resolution of grievances as soon as possible, and suggested that the time frames and notices mirror those applicable to organization determinations (including expedited time frames). Two commenters suggested a 30-calendar day time frame to render a grievance decision, with an opportunity for a 14-calendar day extension for peer review. Both commenters stated that for non-quality of care grievances, both oral and written, M+C organizations should be encouraged to provide personalized service. One commenter believes that if a denial of expedited consideration is considered a grievance, then the grievance procedure must have a mechanism to resolve the dispute within 24 hours, so that an inappropriately denied request for expedited consideration can proceed quickly. Additionally, a commenter asserted that M+C organizations should be required to provide clear, accurate and standardized information concerning grievance and appeal procedures. One commenter asked who will determine which route is more appropriate for the beneficiary in pursuing a remedy to a complaint, since we acknowledge that the same claim or circumstances that give rise to an appeal may have elements of a grievance. This may cause the beneficiary to be unclear as to which route is most appropriate.

Response: Currently, M+C organizations are required under section 1852(f) of the Act and §422.564 to provide "meaningful procedures" for hearing and resolving grievances. In the interim

final rule (63 FR 35030), we requested comments on whether to establish requirements for grievance procedures, and indicated that we would consider prescribing specific requirements for grievances through a forthcoming notice of proposed rulemaking. As anticipated, commenters indicated varying approaches to organization-level grievance procedures. As noted in the interim final rule, we believe that all parties would benefit from subjecting proposed grievance procedures to public notice and comment, and we will do so as part of the notice of proposed rulemaking we are in the process of developing. Thus, we are not including additional grievance requirements in this final rule.

Comment: One commenter disagreed with treating a denial of an expedited determination as a grievance rather than permitting an appeal of such a denial. The commenter argued that such a denial should be considered an adverse organization determination on the health care services an enrollee is entitled to receive, and should be appealable. This commenter contended that denying a request for an expedited determination is not analogous to the example of a grievance provided in the preamble to the interim final rule.

Response: The preamble to the interim final rule cites the regulatory definition of a grievance at §422.561--that is, a grievance is "any complaint or dispute other than one involving an organization determination." The revised definition of

organization determination at §422.566(b) (discussed in detail below) includes determinations regarding payment or services that the enrollee believes should be furnished or arranged for by the M+C organization, and discontinuations of a service if the enrollee believes that the service continues to be medically necessary. In this context, we believe that the term "services" clearly refers to health care services, as opposed to member or customer services, that the M+C organization provides under its contract. Expedited review is a process provided by the M+C organization versus a health care service which is subject to appeal, such as mandatory and optional supplemental benefits. We believe there is a clear distinction between a substantive decision whether benefits should be covered and a procedural decision as to the timing of making such a substantive decision. Indeed, we do not believe that the latter type of determination falls within the statutory language establishing the reconsideration and appeals process, which refers to situations in which the enrollee believes he or she is entitled to services, and to the amount of enrollee liability for services. Therefore, we will continue to require that an organization's denial of expedition generally will be subject to the organization's grievance procedures. We intend to monitor the frequency with which M+C organizations deny requests for expedited determinations.

Comment: One commenter believes that a beneficiary should be able to appeal a disenrollment by an M+C organization, rather than simply being able to utilize the grievance process, as provided in §422.74(d)(2)(ii). In addition, the commenter asserted that decisions on disenrollment should not be left to the M+C organization. Another commenter suggested that we permit a beneficiary to appeal a decision as to whether he or she is entitled to a special enrollment period, and that an M+C organization's decision regarding enrollment or disenrollment, based on the circumstances in §422.62, should be considered an organization determination subject to appeal.

Response: While we do not believe all disenrollment decisions require an appeals process, we recognize the need in some instances, in particular, when a M+C organization disenrolls an individual for disruptive behavior. Accordingly, in §422.74(d)(2), M+C organizations must forward all proposed disenrollments for disruptive behavior to HCFA for administrative review. M+C organizations may not disenroll an individual unless HCFA approves of the decision. With respect to the other, limited circumstances under which a M+C organization has the option to disenroll an individual (that is, failure to pay premiums, or fraud), the enrollee has a right to file a grievance if he or she disagrees with an M+C organization's decision. We believe that this approach to these issues has been proven to be

sufficient over the years. As indicated above, we will monitor M+C organizations' implementation of their grievance procedures to ensure that they are meaningful. Our monitoring will include investigating a complaint from a beneficiary who believes that the M+C organization did not properly handle a complaint about one of the issues discussed by the commenters above.

9. Organization Determinations (§422.566)

Comment: We received numerous comments on various aspects of the definition of an organization determination, including requests for clarification of whether specific types of situations constitute organization determinations. For example, several commenters suggested that reductions in service should be included in the list of actions that constitute organization determinations. The commenters asserted that when services are reduced, beneficiaries receive no notice and are completely unaware of their ability to contest this reduction through the appeals process. Some commenters noted that the vacated 1997 Grijalva order expressly required written notice for a reduction of services. One commenter believes that notice of a reduction in services is of particular importance in the delivery of home care and therapy services. Some commenters believe that §422.566(b)(4), which provides for notice of a termination only if the enrollee disagrees with the determination that the service is no longer medically necessary, is inconsistent with other

Medicare regulations, which the commenter believes require written notice for discontinuation of inpatient services both in a hospital or a skilled nursing facility, regardless of whether the beneficiary agrees with the decision. One commenter suggested that the regulations require M+C organizations to send notices one day in advance of termination, reduction, suspension or delay in services. One commenter suggested that §422.566(b) should include a fifth category indicating that the failure of the M+C organization to approve or provide health care or health care services in a timely manner, or to provide the enrollee with timely notice of an organization determination, constitutes an organization determination. Additionally, some commenters suggested that if, in the future, we require that notices of appeal rights must be given in instances in which the current definition of organization determination is not met, we should incorporate the requirement into the regulations.

Response: As these commenters suggested, we believe there is a need to revise §422.566(b) to provide additional clarity as to the types of situations that constitute an organization determination and thus give rise to the pursuant appeal rights. Therefore, we are revising §422.566(b) as follows:

- Paragraph (b)(1), which concerns payment for out-of-plan services, is revised by adding payment for out-of-area renal dialysis to the existing list of such services (which already

included emergency, urgently needed, and post-stabilization services);

- Paragraph (b)(3) includes additional language to clarify that an organization's refusal to pay for or provide services "in whole or in part, including the type or level of services" can constitute an organization determination if the enrollee believes they should be furnished or arranged for;

- Paragraph (b)(4) is restructured to indicate that a discontinuation of services when an enrollee believes that the services continue to be medically necessary constitutes an organization determination (thus eliminating any implication that an organization must make a formal determination as to medical necessity to give rise to appeal rights); and

- New paragraph (b)(5) is added to specify that another situation that constitutes an organization determination is an MC organization's failure to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or failure to provide the enrollee with timely notice of a determination, if such a delay would adversely affect the health of the enrollee.

Thus, we agree that a reduction in services can be considered an organizational determination that is subject to appeal. To the extent that a reduction results in an enrollee no longer receiving services to which the enrollee believes he or

she is entitled, this would be subject to appeal under the language in the first sentence in section 1852(g)(5) of the Act, which addresses appeals based on failure to receive a health service. Also, since a reduction in services could constitute a "[d]iscontinuation" of services to the extent they were no longer being provided, these cases could fall within the language in §422.566(b)(4). Finally, to the extent that the organization was refusing to continue to provide all or part of the services the enrollee believes should be furnished, and the enrollee has not received the services, this would also fall within the language in §422.566(b)(3).

Examples of other situations that are intended to fall within the clarified definition of an organization determination include:

- A physician requests approval of 10 home health visits, but the organization approves only five visits (even though Medicare allows more than five visits);
- An organization approves a referral to a specialist, but the specialist it designates does not have experience in treating the enrollee's rare condition;
- A physician requests inpatient surgery for a patient because of the patient's history of complications with anesthesiology, but the organization will approve only outpatient surgery; or

- Although an organization agrees to pay for an in-network service, it imposes greater cost-sharing than the enrollee believes is permissible.

We believe that each of these examples fit within the statutory language at section 1852(g)(1)(A) and (B) of the Act that establishes that an M+C organization must have an appeals procedure for determinations as to whether an enrollee "is entitled to receive a health service under this section and the amount (if any) that the individual is required to pay with respect to such service." Thus, the purpose of the revisions to §422.566(b) is not to expand on our interpretation of what types of situations constitute organization determinations but rather to provide additional insight into how we continue to interpret the intent of the applicable statutory provisions.

As we explained above, we are developing a proposed regulation that would provide additional specific guidance as to when a reduction in services gives rise to the obligation to provide a written notice. This has been an extremely difficult issue to resolve, and despite extensive consultations with beneficiary advocates, industry representatives, and State officials, we still have not been able to reach conclusions as to standards beyond those already in the statute and regulations and quoted above. Again, we will address the issue in connection with a separate rulemaking that is being developed in close

consultation with all affected groups. Finally, as commenters suggested, if in the future we believe that it is necessary to require notices of appeal or other rights for situations other than organization determinations, we would do so through notice and comment rulemaking.

Comment: Some commenters requested confirmation that a discontinuation on grounds other than medical necessity is not an organization determination.

Response: As noted above, we have made a minor change to §422.566(b)(4) to clarify that any discontinuation situation in which the enrollee believes that the services continue to be medically necessary constitutes an organization determination, rather than only those situations where a formal medical necessity determination is involved. Moreover, §422.566(b)(3) continues to cover any refusal to provide services (including a refusal to continue to provide services) that the enrollee believes should be provided. While many cases may involve a medical necessity judgment, others may involve a question of how a limit on benefits (including additional or supplemental benefits) applies to given facts. In some cases, the case for noncoverage on grounds other than medical necessity may be so clear-cut that an appeal would not be requested. For example, in a case in which a service is expressly limited to a fixed number of days, and there is no dispute as to how many days the service has been provided,

it is unlikely that the enrollee would "believe" that the M+C organization is obligated to cover days beyond the limit. In other cases, however, there may be ambiguities as to how a limit on benefits is to be interpreted, or applied to a given set of facts, or there may be a dispute as to facts relevant to whether the benefit is covered. In these cases, the beneficiary should have the right to a reconsideration of a denial, so that these issues could be addressed on appeal.

10. Written Notice (§§422.566, 422.568, 422.572, and 422.620)

Comment: Several commenters believe that the regulations at §§422.566 and 422.568 do not make clear that a written notice is required for discontinuations of services.

Response: Except in the case of inpatient hospital care, written notice currently is not required for all discontinuations in services. We believe that our policies on what constitutes a denial in the case of a discontinuation of service (other than in the case of inpatient hospital care) are set forth in the regulations concerning organization determinations. According to revised §422.566(b)(4), discontinuation of a service is considered to constitute an organization determination "if the enrollee believes that continuation of the services is medically necessary." Therefore, if an M+C organization discontinues coverage, and an enrollee indicates that he or she believes that the services continue to be necessary, this action would

constitute an organization determination for which a written notice must be provided. We recognize that there may be circumstances that make it difficult to tell whether a written notice is required in a particular case. We therefore are developing a notice of proposed rulemaking that would address this issue, and clarify rules for M+C organizations and beneficiaries.

Comment: Several commenters suggested that written notice should take place in all instances where services are reduced or discontinued, not only in instances where the enrollee has indicated disagreement. One reason provided for this suggestion is that it would ensure that enrollees always would receive notice of their appeal rights, even if they have not formally objected to the reduction or discontinuation. Another reason given was that this would make the rule consistent with the rule that applies to hospital inpatient discharges. Other commenters suggested that M+C organizations should provide written notice when services actually terminate, or when services discontinue prior to the time for which the M+C organization initially authorized services. Two commenters suggested that we require notice when there are financial implications to the enrollee.

Other commenters supported the current requirement that the M+C organization provide notice when the enrollee disagrees that the services are no longer medically necessary. One commenter

stated that where there is no disagreement, it is wholly inappropriate to provide notice and appeal rights. Instead, it is more appropriate to provide notice at the beginning of a course of treatment. One commenter recommended that we provide advance notice for reductions and terminations in writing, describing the basis for the decision and appeal rights. Some commenters stated that providing detailed notice in all situations would be confusing, burdensome, and intrusive upon the physician/patient relationship. Two commenters recommended we include in this subpart notice requirements for discharge from a SNF.

Response: We recognize that the issue of when it is appropriate for M+C organizations to issue written notice for organization determinations that involve reductions and discontinuations of services is a controversial one. As stated in the preamble to the June 26, 1998 interim final rule (63 FR 35030), we are developing proposed regulations that would further clarify these requirements. At this time, however, we believe that the current regulations serve to balance the need for adequate notice with the potential for inappropriate burdens or beneficiary confusion that might ensue if notice were provided in all cases.

To eliminate confusion, we want to point out that written notice is always required for inpatient hospital discharges

regardless of whether the enrollee agrees with the discharge decision. The issuance of a notice to an enrollee prior to an inpatient hospital discharge required under §422.620 is a separate requirement that should not be confused with the provisions at §§422.566(b)(4) and 422.568(c). We will address the SNF issue in the forthcoming proposed rule.

Finally, as the commenters suggested, we recognize the potential compliance difficulties and burden associated with existing §422.568(c), which requires that if an M+C organization denies services or payment, in whole or in part, it must give the enrollee a detailed written notice that meets the content requirements of §422.568(d) (such as stating the specific reason for the denial and describing the available appeals procedures). We understand that in practice, plan practitioners generally are responsible on behalf of M+C organizations for issuing these detailed notices to their patients, given that most care decisions about future care are made at the practitioner level; and we agree that this practice may be unnecessarily burdensome and intrusive on the practitioner/patient relationship. Moreover, we can understand that requiring M+C organizations to ensure that appropriately detailed notices are given to enrollees in practitioners' offices may be difficult to monitor and enforce in all circumstances.

Therefore, we have revised the provisions at §§422.568(c) through (e) to establish a process under which--(1) practitioners routinely notify enrollees at each patient encounter of their right to receive a detailed notice about their services from the M+C organization itself, and (2) when an enrollee requests an M+C organization to provide a detailed notice of a practitioner's decision to deny a service in whole or in part, or if an M+C organization decides to deny service or payment in whole or in part, the M+C organization must give the enrollee a detailed written notice of the determination, consistent with existing content requirements.

The practitioner's notification must inform enrollees of their right to receive a detailed notice from the M+C organization and provide enrollees with all information necessary in order to contact the M+C organization. Consistent with other notification requirements set forth in subpart M (for example, under existing §422.568(d)(4) or under §422.572(e)(2)(ii)), we also specify that the content of the practitioner's notification must comply with any other requirements established by HCFA. We are now developing standardized language for use by affected practitioners, and will provide an opportunity for public comment through OMB's Paperwork Reduction Act process. Once that process is completed, we intend to provide further guidance on the content and form of the required practitioner notice. We believe

that this requirement will serve to improve M+C organizations' ability to assure implementation of the requirement for detailed written notices while at the same time reducing the administrative burden on practitioners by freeing them from the obligation to routinely provide such detailed notices to their patients.

11. Time Frames (§§422.568, 422.572, 422.590, 422.592, 422.618)

Comment: Several commenters asserted that the standard determination time frames are too long, with some commenters specifically suggesting the time frame of 5 working days that was adopted by a district court judge in a since-vacated March 3, 1997 order in Grijalva v. Shalala (a class action lawsuit filed by Medicare HMO enrollees in 1993, challenging, among other things, the appeals procedures that applied under section 1876 of the Act and part 417). One commenter suggested that upon receipt of complete information, a decision should be rendered within 2 business days. Other commenters stated that the M+C time frames are too short. One commenter suggested that we require M+C organizations to make a good faith effort to meet time frames as opposed to a requirement that M+C organizations must meet absolute time frames. A number of other commenters supported the time frames established through the M+C interim final regulation.

Response: Before deciding to incorporate into the interim final rule reductions in the time frames within which M+C

organizations are expected to render standard organization determinations and reconsiderations for service requests, we consulted with representatives of the managed care industry and beneficiary advocacy community, and conducted extensive research on the subject of organization-level resolution time frames. All groups with which we consulted agreed that the 60-day time frames provided for under the HMO regulations in part 417 were too long. Reports from independent organizations, such as the Physician Payment Review Commission, the General Accounting Office, and medical journals also advocated the reduction of standard time frames. Additionally, we realized the 60-day time frames in part 417 were based on the original fee-for-service Medicare appeals process, which is mostly retrospective. We were aware that new time frames needed to account for the fact that pre-service requests for organization determinations exceed the number of retrospective requests, and that reduced time frames are of critical importance when an individual is awaiting prior authorization for a service. Further, public comments received prior to publication of the M+C interim final rule indicated strong support for a reduction in time frames.

In view of the range of opinions contained in the comments on the M+C interim final rule, we believe that we succeeded in establishing an appropriate middle ground for the maximum time frames. It has also been reported to us that the majority of

organizations make decisions within our reduced time frames. Only one commenter contended that the 14-day time frame could not be met as a general rule. We believe that the opportunity for up to a 14-day extension to the time frames for service-related requests allows the M+C organization adequate time in which to render a determination. We also believe that the new 14 and 30 calendar day time frames are appropriate from both consumer protection and industry feasibility standpoints. The medical exigency standard, which requires that decisions be rendered as expeditiously as an enrollee's health requires, provides for a quicker response where appropriate. Likewise, the opportunity for up to a 14-day extension for both organization determinations and reconsiderations permits M+C organizations additional time to make a coverage decision when appropriate; for example, an M+C organization may extend the time frame at an enrollee's request, or if additional medical documentation is necessary and the M+C organization justifies the reason for the extension.

Comment: Another commenter who advocated reductions to reconsideration time frames suggested that we also reduce the time frame within which M+C organizations are permitted to forward case files to the independent review entity under the standard appeals process.

Response: M+C organizations must forward standard reconsideration cases to the independent review entity within the

time frames permitted for resolution of standard requests. That is, when an M+C organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must make the determination and send the case file for external review as quickly as the enrollee's health condition requires but no later than within 30 calendar days for service requests, or within 60 calendar days for payment requests. Time frames begin on the date the organization received the request for a standard reconsideration. Since time frames for submitting case files to the independent entity are incorporated into the resolution time frames, and we are not reducing time frames for standard reconsiderations, it would not be appropriate to reduce the time frames for submitting information to the independent review entity.

Comment: One commenter stated that we should provide a definition of "good cause" for extensions of time frames. Another commenter suggested that we should clarify that a 14-day extension may be granted in any instance where an organization determination demonstrates a need for additional information.

Response: The regulations for both expedited and standard requests for organization determinations (§§422.568(a) and 422.572(b)) permit an M+C organization to obtain an extension "if the organization justifies a need for additional information and how the delay is in the interest of the enrollee". We believe

that this standard is largely self-explanatory. As indicated in the preamble to the M+C interim final rule, the M+C organization must include written justification of the extension in the enrollee's case file. Although forthcoming operational instructions will provide further clarification of the M+C organization's ability to grant itself an extension, we would like to clarify that a 14-day extension for service-related requests may be granted where an organization finds and notes in the enrollee's case file that it needs additional information to make a determination.

Moreover, to further clarify the grounds on which an M+C organization may seek an extension, and to ensure an enrollee is adequately advised of the M+C organization's use of an extension, we are adding language to both §§422.568(a) and 422.572(b) that requires an M+C organization to notify the enrollee in writing of the reasons for the extension, and to inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision. Relatively few enrollees utilize the appeals process, and most organizations are able to make determinations on requests for services within 30 days. Therefore, we do not foresee that requiring M+C organizations to notify enrollees upon initiating an extension will create an undue burden on M+C organizations.

Comment: Some commenters supported the requirement that M+C organizations must make decisions "as expeditiously as the enrollee's health requires" (the "medical exigency" standard). In contrast, other commenters stated that the medical exigency standard was vague and uncertain, and likely to cause every reconsideration to become expedited.

Response: We believe that the "medical exigency" standard is needed to ensure that M+C organizations will not routinely avail themselves of the maximum time frames for all decisions. Although the expedited review process incorporates the medical exigency standard, this standard is separate and distinct from the process M+C organizations use to handle cases in which a physician or the M+C organization determines that an enrollee's life, health or ability to regain maximum function could be jeopardized in applying the standard time frames.

In our consultations with the public before publishing the M+C interim final rule, industry representatives advised us that each request is different; where some organization determinations are likely to require a 14-day time frame, and possibly 14 additional days, other decisions require less resolution time. Likewise, resolution of some reconsiderations will take up to 30 calendar days, and may require more time to gather additional information. The medical exigency standard requires M+C organizations to prioritize those cases where waiting for a

decision is more likely to affect an enrollee adversely. We interpret this standard as requiring that the M+C organization or the independent entity apply, at a minimum, established, accepted standards of medical practice in assessing an individual's medical condition. Evidence of the individual's condition can be demonstrated by indications from the treating provider or from the individual's medical record (including such information as the individual's diagnosis, symptoms, or test results). We established the medical exigency standard by regulation to ensure that M+C organizations would develop a system for determining the urgency of both standard and expedited requests for services, and give each request priority according to that system. That is, we intend that M+C organizations treat every case in a manner that is appropriate to its medical particulars or urgency, rather than systematically use the maximum time permitted for service-related decisions.

Also, as indicated in the preamble to the interim final rule (63 FR 35028), we continue to believe that the emphasis on the health needs of the individual enrollee is consistent with the statutory requirement that determinations be made on a timely basis. Thus, the fact that an organization makes a determination on a service-related issue within 14 days does not necessarily constitute compliance with the law or regulations if there is

evidence that an earlier determination was necessary to prevent harm to the enrollee's health.

We intend to issue additional guidance on the medical exigency standards in a future operational policy letter.

Comment: Several commenters suggested shortening the maximum time frame for M+C organizations to pay for, or provide, services once the independent review entity has ruled in the beneficiary's favor. One commenter suggested the effectuation time frame should be reduced to 15 days. Another commenter expressed concern that the effectuation requirements in §422.618 do not provide for shorter implementation periods for expedited appeals. One commenter observed that if an M+C organization completely reverses its organization determination on reconsideration of a request for service, the organization must authorize, or provide the service; however, given the fact that the enrollee must seek the service, it may prove difficult to ensure that the service has actually been provided. Thus, this commenter suggested that a letter authorizing the service should be sufficient.

Response: We agree with the commenters concerning the need for a reduction of effectuation time frames for both standard cases overturned upon review by the independent review entity, and expedited cases overturned by the M+C organization or the independent review entity. However, we believe that since M+C

organizations are permitted to authorize, provide or pay for the service in order to effectuate the decision, there is no need to establish a separate requirement for an authorizing letter.

Based on these comments, we are revising §422.618 to reduce the time frame within which M+C organizations must pay for, authorize or provide services to enrollees following a decision rendered by the independent review entity. For service-related requests, the revised language states that "the M+C organization must authorize the service under dispute within 72 hours from the date it receives notice reversing the determination, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from that date." For requests regarding payment, we are reducing the time frame to effectuate the independent review entity's determination from "no later than 60 calendar days" to "no later than 30 calendar days." We continue to maintain a distinction for payment-related appeals because most billing practices are on a 30-day cycle.

We also agree with the comments that expedited effectuation requirements should be incorporated into the regulations. To promote consistency in implementation, and to ensure enrollees receive the services they need as quickly as possible, we are establishing a new §422.619 to require M+C organizations to effectuate overturned, expedited determinations as quickly as

necessary, but no later than within 72 hours. Under the new provision, if the M+C organization reverses its original adverse organization determination, in whole or in part, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the date it receives the request for the determination.

Where the independent entity reverses, in whole or in part, the M+C organization's initial expedited determination, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the date it receives notice reversing the determination. In instances where the independent review entity expedites certain cases on its own accord (for example, where an enrollee or physician did not originally request an expedited appeal at the M+C organization level, but the independent review entity determines an expedited appeal is warranted), the expedited effectuation requirements of §422.619 still apply.

If the ALJ or higher level reviewer reverses the independent review entity's expedited reconsidered determination, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health requires, but no later than 60 calendar days from the date of the decision.

Comment: Several commenters urged that we incorporate the review time frames for the independent review entity into the regulations text. Section 422.592(b) provides that an independent outside entity must conduct reconsideration reviews "as expeditiously as the enrollee's health condition requires but must not exceed the deadlines specified in the contract." One commenter noted that the contract with the independent outside entity may change each time it is negotiated, and that the general public is not informed of such negotiations, or the time frames produced by these negotiations. Thus, this commenter believes that regulations should specifically impose appropriate time limits on the independent review entity, and the time limits should be consistent with those specified in the vacated 1997 Grijalva order. One commenter expressed concern that the public has no remedy when the independent review entity fails to comply with time frames in the contract. This commenter added that the public plays no role in contract negotiation through which the independent review entity's time limits will be determined; and therefore, there is no assurance that an appropriate time limit will be imposed. One commenter recommended that we contract with PROs for the expedited review process instead of our current contractor, the Center for Health Dispute Resolution (CHDR). (PROs are organizations under contract with us to perform utilization and quality review of Medicare services generally,

and review of the quality of services furnished by M+C organizations to their enrollees.) There was also concern about the notices provided by the independent review entity. Some commenters suggested that §422.594 specify that the notice should be written in "understandable language," as provided in §422.568. Additionally, these commenters believe that the notice should also inform the enrollee about the PRO complaint process under section 1154(a)(14) of the Act.

Response: The time frames for the independent entity's review currently are the same as those time frames within which M+C organizations are required to decide standard and expedited cases, as detailed in the chart provided in the interim final rule (63 FR 35024). The time frames appear in our contract with the independent entity (as opposed to the regulation), however, to provide flexibility in the case of an unanticipated increase in the volume of appeal cases--since the independent contractor reviews cases from organizations nationwide. We have provided public notice of the time frames in the interim final rule and again in this rule. We agree with the commenters that beneficiaries should be informed of any changes that we might make to the current time frames, and will inform beneficiaries if these time frames are changed.

Additionally, we agree with one of the recommended changes to the independent entity's reconsideration notice, and are

amending §422.568 to require that the notice be written in "understandable language." We also will consider issuing instructions to require the independent entity to advise an enrollee of his or her right to review by the PRO for quality of care concerns; (the same requirement on M+C organizations is set forth via model notice instructions).

12. Expedited Organization/Reconsidered Determinations
(§§422.570, 422.572, 422.584, and 422.590)

Comment: Several commenters expressed concern with §422.572(d), which provides that the 72-hour time period under §422.572(a) does not begin until medical information is received from noncontract providers where such information is required. One commenter stated that such an open-ended requirement poses an unreasonable risk of delay for the enrollee; especially in cases where time is of the essence, this provision could allow a decision to be postponed indefinitely. Another commenter suggested that M+C organizations should be required, at a minimum, to contact the noncontract provider within 24 hours of the initial request for an expedited reconsideration in order to request the necessary information from the noncontract provider and provide a fax number where the information can be submitted. Additionally, the commenter suggested that the enrollee, the representative, and the physician should be contacted to: explain the delay, inform them of the information needed, and

provide them with a fax number. One commenter stated that the regulations should place the burden on the M+C organization to make prompt, good faith efforts to communicate with the noncontract provider to obtain the needed information.

Additionally, information from noncontract providers should be provided within the 14-day extension period and under the same conditions that an extension would be granted in other circumstances. However, one commenter stated allowing an M+C organization to grant itself a 14-day extension beyond the 72-hour time frame gives the M+C organization too much additional discretion. This commenter stressed that an M+C organization will always state that it needs more than 72 hours, particularly if treatment will be expensive.

Response: We largely agree with the commenters, and are revising the regulation text to ensure that M+C organizations must make determinations within the same expedited time periods for cases involving noncontract providers. Accordingly, we are revising §§422.572(d) and 422.590(d)(4) to eliminate the provisions indicating that the 72-hour period begins when the organization receives information from the noncontracting provider. Instead, the regulations will require the organization to meet the same time frames set forth in §§422.572(a), (b), and (f) for expedited organization determinations and §§422.590(d) and (f) for expedited reconsiderations regardless of whether the

M+C organization must request information from noncontracting providers. We agree that in situations where either a physician or the M+C organization has already determined that an expedited decision is crucial, open-ended time frames may put the enrollee at risk. We likewise are incorporating into §422.572(d) the recommended provision for expedited reviews that requires the M+C organization to request any necessary information from the noncontract provider within 24 hours of the initial request for expedition. We continue to require noncontract providers to make "reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the M+C organization in meeting the required time frames." We believe an opportunity for an M+C organization to take up to a 14-day extension under the 72-hour expedited review process provides the M+C organization with a reasonable opportunity to obtain information from non-contract providers. We will monitor M+C organizations to ensure M+C organizations do not routinely, or unnecessarily, avail themselves of the 14-day extensions. Where appropriate, M+C organizations must notify the physician involved; M+C organizations are always required to notify enrollees of the decision, whether the decision is adverse or favorable to the enrollee, in accordance with the regulation. However, we do not agree that the M+C organization must always contact or notify the enrollee's physician.

Comment: Several commenters stated that the criteria for deciding whether a determination must be expedited may be too rigorous. Some commenters suggested that we revise §§422.570(c)(2) and 422.584(c)(2) to reflect language from the district court's vacated order in the Grijalva case, under which reconsiderations were to be expedited "when services are urgently needed." The district court provided the examples of when acute care services are being denied or terminated, certain types of nursing facility care, certain types of home health and therapy services, and denials of certain types of non-cosmetic surgery. This commenter suggested that the regulation state that expedited consideration may be granted, in certain circumstances, upon lay evidence and without a request by the physician. One commenter contended that the regulations should clearly articulate what constitutes "seriously jeopardizing the enrollee's life, health, or ability to regain maximum function." The commenter argued that a more specific definition should be provided that takes into account both a substantial risk of an adverse outcome, and a small (but significant) risk of a serious and adverse outcome such as permanent disability or death. Some commenters expressed concern that if an enrollee does not obtain physician support to expedite a determination, the M+C organization has broad discretion in deciding whether to expedite.

Response: We do not believe that the adoption of the "urgently needed" standard from the vacated Grijalva order would be appropriate. First, we believe it is too broad and vague. Second, the term "urgent" is already used in connection with "urgently needed services" (for which enrollees do not need to obtain prior authorization). Using the same term here could cause unnecessary confusion. We also believe that the "serious jeopardy" standard is sufficiently clear. It is unclear how we could expand on what is meant by "serious jeopardy" to an enrollee's "life" (that is, could put his or her life in serious jeopardy), "health" (that is, could put his or her health in serious jeopardy), or "ability to regain maximum function" (that is, could put his or her ability to regain maximum function in serious jeopardy). We believe that the commenter's suggestion that the requirement to expedite a case in which there is a "significant" risk of a "serious and adverse outcome such as permanent disability" is already addressed in language referring to "seriously jeopardizing the enrollee's. . . ability to regain maximum function." With respect to the commenter's suggestion that the regulations provide for cases to be expedited based on "lay evidence" (that is, in the absence of the involvement of a physician), this is already required under section 1852(g)(3)(B)(ii) of the Act "if the request indicates that the application of the normal time frame for making a determination

(or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function." The interim final rule and this final rule similarly provide for expedition without the need for a physician's involvement. (See §§422.570(a) through (b), and 422.584(a) through (b).) Although this decision is made by the M+C organization in the absence of a physician's involvement, the decision is subject to the grievance process, and we will monitor M+C organizations closely to ensure that they are expediting cases where appropriate.

Comment: Several commenters strongly urged the removal of the requirement that physicians requesting an expedited appeal must be acting as an enrollee's authorized representative. Commenters contended that the regulation as written is inconsistent with their view of statutory intent, intrudes in the doctor-patient relationship, and could present a problem for incapacitated enrollees.

Response: We agree that a physician who requests an expedited reconsideration on behalf of an enrollee should not have to be formally appointed as the enrollee's authorized representative. We initially included this provision based on our belief that the physician served a different role in the context of an organization determination versus an appeal. In the case of an organization determination, we regarded the

physician as a provider who is requesting a service for his or her patient. On the other hand, in the context of a reconsideration, we viewed the physician as serving as the enrollee's representative in the first level of the appeals process. Thus, we believed the physician would need to be appointed by the enrollee in the same manner as any one else who served as a representative. However, in response to the above comments, we have reconsidered our position, and recognize the operational problems with requiring that physicians be authorized representatives when requesting expedited reconsiderations on an enrollee's behalf. For example, under the M+C program, each appeal request requires completion of a separate authorized representative form, which may cause an undue burden on physicians. For this reason and those set forth in the comment above, we have decided to revise §422.584(a) by eliminating this requirement. Therefore, physicians may request expedited reconsiderations on a patient's behalf without being appointed as the enrollee's authorized representative.

We want to make clear, however, the distinction between a physician acting on behalf of the enrollee, and a physician who meets the conditions for being a party in his or her own right. When a physician seeks either a standard or expedited organization determination for services on behalf of the enrollee, the physician does not need to be an authorized

representative. But, if the physician seeks a standard reconsidered determination for purposes of obtaining payment, then the physician must sign a waiver of liability, consistent with §422.574(b).

Comment: One commenter suggested that the ability to request an expedited organization determination should be expanded. The commenter suggested the following options for expansion: (1) all health care professionals, (2) health care professionals that have been designated by a physician to carry out such tasks, or (3) all health professionals providing care in medically underserved areas. Another commenter suggested that we should permit an "authorized representative" to request an expedited determination.

Response: The statute explicitly lists enrollees and physicians as those permitted to request expedited organization determinations and expedited reconsiderations, (see sections 1852(g)(3)(a)(1) and (2) of the Act). We note that authorized representatives may request expedited determinations or reconsiderations, since the definition of "enrollee" in §422.561 includes the enrollee's authorized representative. Therefore, the regulations already permit health care professionals who enrollees authorize as their representatives to request expedited organization determinations and expedited appeals. As described in the previous comment, physicians now

may make requests without being authorized representatives. We do not believe it would be appropriate, however, to grant health care professionals other than the enrollee's physician the right to make requests on the enrollee's behalf absent an authorization. There are so many potential health care professionals involved in a patient's care, this could create confusion, and potentially cause duplicate or conflicting requests.

Comment: One commenter suggested that we incorporate a separate notice requirement provision whereby, before deciding whether to expedite a determination, the M+C organization must notify the enrollee of the M+C organization's obligation to expedite any request for a determination that was accompanied by a physician's statement that "applying the standard time frame for making a determination could seriously jeopardize the life of the enrollee or the enrollee's ability to regain maximum function." Several commenters requested that we define "prompt oral notice" of a denied request for expedition, as provided in §422.570(d)(2). This section provides that, if the M+C organization denies a request for an expedited determination, it must give the enrollee prompt oral notice of the denial and follow up within 2 working days with a written letter explaining their right to file a grievance. One commenter asked whether this meant the enrollee is supposed to receive the written notice

within 2 working days of the decision, or that the organization is to mail it within 2 working days. Additionally, the commenters suggested that this section also specify that the enrollee be given the right to make an oral, immediate request for a reconsideration when given oral notice of denial, followed by written verification of the reconsideration request.

Response: M+C organizations are required under §422.111(a)(8) to provide notice of grievance and appeal rights upon enrollment and at least annually thereafter. Thus, all enrollees should receive notice of the right to automatic expedition of determinations and reconsiderations when a physician supports the request. However, in a case in which an enrollee submits a request for an expedited organization determination or an expedited appeal, but does not indicate that the request was supported by a physician, we recognize that the enrollee may not have read the required notice carefully, and thus be unaware that a physician's support would make the expedition of the request automatic. We therefore are revising §§422.570(d)(2) and 422.584(d)(2) to require that when an M+C organization denies a request for an expedited determination or reconsideration, its notification letter must inform the enrollee of the right to resubmit the request with a physician's support.

As noted above, upon denial of an enrollee's request for expedited review, existing regulations require an M+C

organization to provide the enrollee with "prompt oral notice" of the denial, and follow up with a written letter within 2 working days. We believe that this is a reasonable requirement which indicates that an M+C organization must contact and advise the enrollee of the denial without delay. As suggested by the commenter, we are clarifying the regulations to indicate that subsequent to providing oral notice of the denial, M+C organizations must "deliver" to the enrollee, within 3 calendar days, a written letter that includes the information listed in the regulation at §§422.570(d)(2) and 422.584(d)(2). We interpret this provision as requiring an M+C organization to first orally notify an enrollee of a denial, and subsequently deliver written notice to the enrollee within 3 days after the decision. Note that we have revised the regulations at §§422.570(d)(2), 422.572(c), 422.584(d)(2), and 422.590(d)(3) to establish a requirement of 3 calendar days, rather than 2 working days. We believe this is a reasonable amount of time within which to require M+C organizations to deliver written notice enrollees (following the oral notice) of a denied expedited request, and that the change to calendar days will eliminate confusion over what constitutes a working day. This change is consistent with the general replacement of standards related to "working days" with "calendar day" standards throughout the M+C regulations.

We also wish to clarify that if an enrollee's request for an expedited organization determination is denied, the M+C organization will automatically transfer and process the enrollee's request under the standard process. If the M+C organization denies the request in whole or in part, the enrollee (or a physician on the enrollee's behalf) then has a right to orally request expedited reconsideration. The M+C organization continues to be responsible for documenting all oral requests in writing and maintaining the documentation in the case file.

13. Authorized Representative (§§422.561 and 422.574)

Comment: A commenter suggested that §422.574, which addresses parties to the organization determination, should include surrogates under State law as a possible party to an organization determination. This commenter added that by excluding such surrogates, enrollees who are incapacitated and cannot appoint representatives may lack persons authorized to handle appeals on their behalf. Similarly, two other commenters stated that the "authorized representative" definition should be expanded to allow individuals who can act on behalf of an individual under State law to be authorized representatives. This commenter believes that the current definition is limited to an individual appointed under the Social Security Act, and requires completion of the Appointment of Representative form. The commenter believes that this requirement makes it difficult

for those who have written Durable Power of Attorney to act in place of the beneficiary. Several commenters suggested that the definition of "enrollee" should not include an authorized representative. One commenter argued that an authorized representative is not the enrollee, since an enrollee is someone who is entitled to health services. Further, the commenter recommended that an authorized representative receive copies of all communications sent to the enrollee concerning the appeal.

Response: We agree with the commenters concerning the need to include those individuals appointed under State law (such as surrogates) in M+C requirements, as well as those with Durable Power of Attorney. For this reason, we are amending the definition of authorized representative at §422.561 to include an individual authorized by an enrollee, "or under State law," to act on his or her behalf in obtaining an organization determination, or in dealing with any of the levels of the appeals process, subject to the rules described in 20 CFR part 404, subpart R, unless otherwise stated in subpart M. We believe that the revised definition of an authorized representative includes those individuals with Durable Power of Attorney. Therefore, an individual authorized to act as a surrogate of an enrollee and those who have written Durable Power of Attorney are permitted to act on behalf of an enrollee in the organization determination, reconsideration and appeal processes. By adding

individuals authorized under State law to the definition of authorized representative, such individuals are included as one of the parties to an organization determination listed at §422.574, since the definition of an enrollee (who is a party) includes the enrollee's authorized representative. Thus, a surrogate authorized by the State is not only a party to the organization determination, but is permitted to act on behalf of the enrollee under all provisions of subpart M.

We disagree with the commenters who requested that the definition of "enrollee" exclude an authorized representative. Although we recognize that an authorized representative is not an enrollee in the literal sense of being entitled to health services, we believe that to ensure authorized representatives are always permitted to act on behalf of an enrollee, the regulations should include an authorized representative in the definition of "enrollee" under subpart M. We note that §422.561, which sets forth the definitions used in the appeals regulations contained in subpart M, specifies that the definitions are only "as used in this subpart, unless the context indicates otherwise."). An authorized representative thus would not be considered an enrollee for general M+C program purposes, such as under enrollment or financial liability provisions, but would be able to exercise the rights available to an enrollee for appeal and grievance purposes, such as the right to act on behalf of an

enrollee in requesting an appeal or to receive applicable notifications.

Comment: One commenter commended our appeal and grievance rights as providing substantial protection, yet expressed concern over access for enrollees with special health care needs (the disabled and/or chronically ill). One commenter stated that M+C organizations will face a challenge in serving the increasing population of beneficiaries with questionable, fluctuating or diminished capacity, and further stated that M+C organizations need to identify enrollees who have surrogates in order to keep them informed. This commenter stated that the regulation should require information and notices be sent to surrogates of incapacitated beneficiaries, and surrogates should be listed as requesters of expedited decisions.

Response: As noted above, to the extent that such a surrogate is authorized under State law to act on the beneficiary's behalf, he or she would be considered an authorized representative who is included in the definition of enrollee and permitted to make requests on the beneficiary's behalf. With respect to other additional procedural protections for enrollees with special health care needs, we believe that such additional protections for enrollees with special health care needs should be included in a notice of proposed rulemaking to provide the public with ample opportunity for input on final standards. We

plan in this rulemaking to address the issue of special protections for beneficiaries with limited capacity, and consider possible additional notice requirements for surrogates in such cases.

14. Other Appeal Rights (§§422.596, 422.600, 422.602, 422.608, 422.612, and 422.616)

Comment: One commenter suggested that we revise §422.596 to clarify that an M+C organization cannot appeal to an Administrative Law Judge (ALJ). However, two commenters argued that M+C organizations should have the right to appeal to an ALJ.

Response: Section 422.600 addresses the "Right to a hearing." Section 422.600(a) provides that "any party to the reconsideration (except the M+C organization) who is dissatisfied with the reconsidered determination has the right to a hearing before an ALJ." (Emphasis added.) Section 422.600(a) then expressly states that "[t]he M+C organization does not have the right to request a hearing before an ALJ." While we believe that the regulations thus are already clear on this point, we have no objection to the commenter's suggestion that §422.596 be revised to also reflect this restriction.

The policy limiting ALJ appeal rights to Medicare enrollees has been in place since the inception of the Medicare risk contracting program under section 1876 of the Act. As noted above, under section 1856(b)(2) of the Act, M+C standards are to

be based on standards established under section 1876 of the Act to the extent consistent with M+C rules. More importantly, the M+C statute expressly grants a right to a hearing only to an enrollee, with the M+C organization given the right to: (1) be made a party to such a hearing; and (2) appeal from an ALJ.

Section 1852(g) of the Act sets forth a three step process for appeals of coverage determinations. Section 1852(g)(1) of the Act establishes the process for making initial organization determinations and providing notice of appeal rights. Section 1852(g)(2) of the Act provides for the reconsideration process, which is conducted initially by the M+C organization. (Section 1852(g)(3) of the Act provides for M+C organizations to expedite certain organization determinations under section 1852(g)(1) of the Act and reconsiderations under section 1852(g)(2) of the Act; and section 1852(g)(4) of the Act provides for review by an independent review entity as part of the reconsideration process established under section 1852(g)(2) of the Act). It is section 1852(g)(5) of the Act which provides for the ALJ level of review if the amount in controversy is at least \$100, and for ultimate judicial review. Under section 1852(g)(5) of the Act, "[a]n enrollee with a Medicare+Choice organization. . . is entitled (if the amount in controversy is \$100 or more) to a hearing before the Secretary...and in any such hearing the Secretary shall make the [M+C] organization a party."

Comment: A commenter suggested that some denied services that do not reach the \$100 threshold represent legitimate disputes that could adversely affect patients. This commenter believes that patients should be able to request ALJ hearings for denials of services needed to maintain or regain health or physical functions, without regard to the cost involved. Another commenter similarly asserted that an enrollee's ability to obtain an ALJ hearing and seek judicial review should not be based on the amount in controversy, because this could arbitrarily prevent some enrollees with legitimate disputes from appealing. This commenter suggested modifying the provision to allow a decision to be appealed if the amount in controversy meets the identified threshold, or if the patient's life or health may be jeopardized as a consequence of the decision.

Response: Although we are sensitive to the concerns of the commenters, amount in controversy (AC) requirements in the case of appeals under the M+C program are set forth in the statute at section 1852(g)(5) of the Act. A statutory change would be required to alter the current threshold levels; therefore, we are not modifying the M+C regulations.

Comment: A commenter expressed concerns about the process for obtaining judicial review. The commenter also requested clarification as to what constitutes the "final decision of HCFA." The commenter believes that some enrollees may not have

the resources to pursue their rights in court. This commenter recommended that the reimbursement of attorney fees or associated court costs be left to the discretion of the judge performing the judicial review.

Response: A decision by our agent, the independent review entity, becomes "final" and binding on all parties unless a party other than the M+C organization files a request for an ALJ hearing, or unless the decision is reopened and revised by the independent entity. This is the earliest "final" decision that involves us (through our agent), since organization determinations are made by M+C organizations. If this decision is not appealed or re-opened, it is in essence, a "final decision of HCFA." A failure to appeal this decision, however, would mean that the right to further administrative and judicial review has been forfeited. An ALJ decision is similarly final and binding if it is not appealed by a party; (unlike a reconsidered determination, an M+C organization has the right to appeal an ALJ decision). If a timely appeal is filed, the ALJ decision is subject to further review by the Departmental Appeals Board (DAB). At this point, if the DAB declines to review the case, under §422.612(a), the ALJ's decision becomes a "final" decision for purposes of the right to judicial review. If the DAB agrees to hear the case on appeal, the DAB's decision is the "final decision of HCFA" for purposes of judicial review.

We believe that the commenter's confusion about what constitutes a "final decision of HCFA" may be due to some confusing regulatory text in §422.612(b). Section 422.612(b) provides that a decision of the DAB may be appealed to Federal court if "(1) It is the final decision of HCFA; and (2) The amount in controversy is \$1,000 or more." This implies that there is a distinction between a DAB decision and a "final HCFA decision." In fact, a DAB decision constitutes a "final decision" on our behalf, since it is not subject to any further administrative review. We therefore are revising §422.612(b) to provide that a DAB decision may be appealed to district court if the amount in controversy is \$1,000 or more.

Comment: One commenter suggested that we include other rights found in State managed care laws, such as requiring M+C organizations to provide beneficiaries, on request, with clinical guidelines upon which a denial is based.

Response: M+C organizations must provide enrollees with written notice of the reasons for a denial, as set forth at §§422.568(c) and (d). This includes providing all the information necessary for the beneficiary to understand why the service was denied, including any Medicare coverage criteria or policies applied in making the decision, as well as specific clinical rationales if applicable. To the extent that particular guidelines or screens are used in the determination process, but

are not determinative of coverage (for example, services falling outside certain screens will be given closer review, but still covered if coverage standards are met), we do not believe it is critical for beneficiaries to have access to these documents. We note that Medicare does not make similar documents used by carriers and intermediaries under the fee-for-service program available to the public.

15. Inpatient Hospital Notice of Discharge (§§422.580, 422.586, 422.620 and 422.622)

Comment: Two commenters urged that we simplify the language used in the notice of noncoverage (hereafter referred to as the Notice of Discharge & Medicare Appeal Rights (NODMAR)). One commenter suggested working with us to craft a notice outlining beneficiary rights of appeal while avoiding unnecessary paper work, especially since most of the NODMAR information is already contained in the "Important Message From Medicare" issued upon admission to a hospital. One commenter stated that the notice should be on a clear and readable form, in at least 12-point font, and in understandable language. One commenter stated that beneficiaries are confused by the content and intent of the notice, and that the notice should include a contact person at the M+C organization. Two commenters stated that this should be a form developed by HCFA.

Response: Shortly after the promulgation of the notice requirement, which is reiterated in §422.620, we began receiving comments that the notices of noncoverage being issued to beneficiaries were confusing, contained a great deal of sophisticated "legalese," were too long (the notices were ranging from five to nine pages), and that the many variations of the document posed administrative burdens. Therefore, we committed to drafting a more comprehensive and beneficiary-friendly notice.

We began consulting with industry groups, beneficiary advocacy groups, and peer review organizations in support of drafting a notice that would serve the intended purpose. On February 11, 1999, we issued OPL 99.082. This OPL conveyed: (1) our new notice, the NODMAR; (2) our intent to consumer test and standardize the model language; and (3) our continued effort to find the best balance of beneficiary protections with administrative burden. The model language conveyed in the OPL contains language that is in 12 and 14-point fonts, is written in understandable language, and is only three pages in length.

The Important Message from Medicare (IMM) and the NODMAR are two documents that contain similar information. The IMM is currently given to the Medicare beneficiary at or about the time of admission, while the NODMAR is given in advance of the patient's discharge. We recognized the burden associated with issuing two notices with similar information. Therefore, we have

developed a single document and process that allows patients to be informed about their inpatient hospital rights at a time and in a form that will be most beneficial to them and in a manner that reduces administrative burden. This single document is a revision to the existing Important Message from Medicare.

Accordingly, we have revised the IMM to provide for the inclusion of information on patients' inpatient hospital discharge rights. All Medicare beneficiaries will receive a revised notice, the "Important Message About Medicare Rights: Admission, Discharge, & Appeals," as required under section 1866(a)(1)(M) of the Act.

This revised standardized form will be issued to all Medicare beneficiaries who are inpatients of a hospital at or about the time of their admission. Once a Medicare beneficiary's time of discharge is determined, an amended notice that includes the reasons for the discharge would again be provided to the beneficiary prior to his or her actual discharge. The revised Important Message About Medicare Rights: Admission, Discharge, & Appeals has been consumer-tested, and has received favorable feedback. (Pursuant to the Paperwork Reduction Act of 1995 (PRA), a notice outlining this document was published in the Federal Register on April 12, 2000, with public comments accepted through June 12, 2000. See 65 FR 19783.) The content of the revised notice (and amended follow-up notice) will meet the

requirements of the PRA and section 1866(a)(1)(M) of the Act (the Important Message from Medicare), and the notice requirements set forth at §422.620 that are now contained in the NODMAR.

Comment: One commenter stated that the notice should include standardized language that indicates that review by PROs is usually preferable to a plan review, and should clearly explain that the enrollee is obligated to make a request in this fashion under these tight time restraints in order to be protected from financial liability.

Response: As explained in the preamble to the June 26, 1998 interim final rule, there are advantages to filing for immediate PRO review. The most significant advantage in utilizing the immediate PRO review process is protection from financial liability for a continued hospital stay until noon of the calendar day following the day the PRO notifies the enrollee of its review determination. In addition, the immediate PRO review process offered the enrollee direct communication with the PRO and a decision that is generally rendered more quickly than an M+C organization's determination.

Therefore, when the model language, NODMAR, was drafted, we included language that would allow the enrollee to understand the significance of meeting the immediate PRO review deadline. Likewise, the revised Important Message stipulates that if the enrollee meets the deadline for filing for immediate PRO review,

the enrollee's M+C organization continues to be responsible for paying the costs of the enrollee's hospital stay until noon of the day after the PRO notifies the enrollee of its official decision.

In addition to stating that the enrollee has financial protection if he/she meets the immediate PRO review deadline, we have included a section that explains what happens to the enrollee if he/she misses the deadline and has to appeal to the M+C organization.

Comment: One commenter strongly supported the M+C regulations that improve notice requirements for hospital discharges. The commenter stated that the requirement that hospitals provide notice at the time of discharge instead of at admission gives M+C enrollees an additional protection against premature discharges. One commenter stressed the importance of always issuing a notice with respect to termination of any form of inpatient care, even when the enrollee has not expressed disagreement, because these are such significant changes in circumstances. The commenter suggested that these notices must be given in advance of the termination, and inpatient care must continue, without financial liability to the enrollee, until the appeal is resolved.

Response: We agree with the commenter that a notice of appeal rights should be issued at discharge without regard to

whether the beneficiary expresses disagreement with the termination of care. Section 422.620(a) already provides that an M+C enrollee has the right to continued coverage of inpatient hospital services unless a proper discharge notice is provided. We are concerned that the commenter appears not have understood the existing regulations to require a notice in all cases. This misinterpretation of our current requirements is consistent with what we have heard from beneficiaries discharged from hospitals during the year prior to consumer testing conducted on the NODMAR, who reported that they were unaware that they had the right to appeal the decision that it was time to leave the hospital, and left based on the belief that they had no choice in the matter. Given that the existing regulations text may not be sufficiently clear, we are responding to this comment by revising §422.620(a) to expressly require that written notice be issued to enrollees in the case of all discharges and by revising the introductory clause in §422.620(c) to provide that "In all cases in which a determination is made that inpatient hospital care is no longer necessary, no later than the day before hospital coverage ends, each enrollee must receive a written notice that includes the following...."

With respect to the commenter's suggestion that the enrollee not be financially liable until an appeal is resolved, as noted above, if the enrollee disagrees with a discharge decision, the

enrollee may file for immediate PRO review by noon the day after a discharge notice is received. If such a timely request for review is filed, the enrollee is protected from financial liability until at least noon on the day after notice of the PRO's decision, if the PRO upholds the decision to discharge the enrollee. If the PRO decides that hospital services are still necessary, coverage would continue until a new discharge notice is issued.

Comment: Several commenters did understand the current regulations to require issuing the NODMAR to every enrollee prior to being discharged from an inpatient hospital setting, and indicated that they found this requirement difficult to administer. One commenter believes that M+C organizations need the cooperation of hospitals to fulfill this requirement, and contended that such cooperation was not always possible to obtain. Therefore, this commenter suggested that we reconsider our decision to require that a NODMAR be provided to every M+C organization member prior to discharge, or that we at least articulate this requirement as a "good faith effort" versus an absolute requirement. Two commenters said that in cases in which the responsibility for providing the notice has not been delegated by the M+C organization to the hospital, or where hospitals refuse to assist in this process, M+C organization staff would have to be available to visit each hospital on an

ongoing basis 7 days each week, thereby creating a significant increase in the level of staffing. One commenter reported that in some cases, hospitals are demanding compensation from M+C organizations for providing the notice to enrollees. Another commenter contended that it is inappropriate and unhelpful for hospitals to issue the notice, since there is no reimbursement from M+C organizations or Medicare, and it is impossible for hospital staff to explain decisions they did not make.

Response: We understand the burdens associated with an M+C organization directly providing notices in a hospital setting, and agree with the commenters who stated that hospitals are in the best position to give the discharge notice required under §422.620. In light of the above comments, we have completed development of a single document that combines the NODMAR with the "Important Message." (The Important Message is the document we have determined that hospitals are already required, under section 1866(a)(1)(M) of the Act, to issue to all Medicare beneficiaries, including M+C enrollees.) While this regulation is not the appropriate vehicle to impose requirements on hospitals, some of which do not contract with M+C organizations, we intend, through a more appropriate vehicle, to require that all hospitals provide discharge notices for all Medicare patients. Thus, we are revising §422.620 to eliminate the

existing requirement that M+C organizations issue the notice of noncoverage to M+C enrollees.

Lastly, we note that it is the responsibility of the entity that made the discharge decision to ensure that an enrollee's questions about the discharge decision be directed to someone within that entity who can provide assistance. Thus, where a discharge decision is made by an M+C organization, that organization should be available to answer questions, even though the notice is issued on the organization's behalf by a hospital.

Comment: Several commenters suggested that the requirement to issue a NODMAR to all enrollees prior to discharge should be repealed or significantly modified. Four commenters suggested that the NODMAR should be given only if the enrollee or the physician disagrees with the hospital's decision to discharge. One commenter contended that issuing a notice in cases where the enrollee agrees with the discharge decision is unnecessary, will confuse the enrollee, and may result in the delay of appropriate discharge or the increase in hospital costs.

Response: The intent of the notice requirement set forth at §422.620, as with all notice requirements, is to provide enrollees with information that will help them make an informed decision about their health care at a time when it would be most needed and effectively received. The notice requirement is an important and necessary beneficiary protection.

Again, the revised Important Message has undergone extensive consumer testing. This has helped us to improve the content of the notice to make it less confusing to the beneficiary. Since the revised notice will be used to satisfy the requirement for notice of discharge/termination of coverage, beneficiaries will have the benefit of the consumer testing in this context as well.

Comment: One commenter supported an extension of the notice requirement to original Medicare beneficiaries, that is, all Medicare beneficiaries would receive a notice prior to being discharged from the hospital regardless of whether the beneficiary agrees with the decision. The commenter stated that until this requirement is extended, it will be very difficult to achieve full compliance, and urged that we defer any evaluation of plan compliance with this requirement until such an extension is secured.

Response: We have received many inquiries as to whether the M+C policy of issuing NODMARs in all cases will also apply to original Medicare beneficiaries. Currently, the practice has not been for hospitals to issue notices (that is, the Hospital-Issued Notices of Noncoverage (HINN)) to all original Medicare beneficiaries in advance of their hospital discharge, but to do so only in cases in which the beneficiary disagrees. We believe that it is in the best interests of all Medicare beneficiaries and the entities responsible for distribution of such notices to

implement a uniform policy for M+C program and original Medicare purposes, and we intend to provide for this through an appropriate vehicle. This final rule, however, sets forth only those requirements that apply in the case of M+C enrollees.

Comment: One commenter contended that our inpatient hospital notice requirement generates ill will among M+C organizations, contracting providers, and beneficiaries. Two commenters opposed the notice requirement because they believe it would raise costs to hospitals.

Response: The intent of the notice requirement is not to supplant the doctor/patient relationship nor to harm the working relationships among M+C organizations, contracting providers, and/or beneficiaries. We believe that standardized instructions, and the eventual implementation of a uniform policy for original Medicare beneficiaries, will help to alleviate a great deal of contention between the various entities. In the long run, this should make the referenced relationships function more smoothly.

Comment: One commenter suggested that the regulation should make clear that if a notice is not issued, the M+C organization (not the hospital) is liable for services.

Response: We agree that if proper notice is not provided, the M+C organization is liable for coverage, unless the hospital has been delegated the authority to make coverage decisions on behalf of the M+C organization. This liability is provided for

under §422.622(c), which expressly addresses liability for services, and §422.620(a), which makes clear that the enrollee is entitled to coverage until noon the day after notice is given.

Comment: One commenter suggested that the only information that should be reviewed in an appeal of a decision not to admit a patient to a hospital, or to discharge a patient, is that which was available at the time that the decision was made.

Response: We disagree with the commenter. We believe that the entity reviewing an inpatient hospital discharge decision, or decision not to admit an enrollee to the hospital, should base its review on all the facts and evidence available--regardless of whether such information was available at the time of the decision not to admit or to discharge. In particular, in the case of review by the M+C organization, §422.586 provides the parties to the reconsideration with an opportunity to present related evidence and allegations of fact or law in person as well as in writing; (the regulation notes that such an opportunity may be limited in the case of expedited reconsideration). Further, §422.580 defines a reconsideration as a review of an adverse organization determination, the evidence and findings upon which it was based, and any other evidence the parties submit or the M+C organization or we obtain. Thus, there is ample precedent for not limiting information to be reviewed in the case of an appeal, and we plan to continue that policy.

Comment: One commenter suggested that, in order to avoid stalemates, the M+C regulations (like the original Medicare regulations) should provide a process to resolve cases in which the physician and the M+C organization disagree about the discharge decision.

Response: We agree with the commenter that the existing regulations do not provide for a clear resolution process in situations where an M+C organization determines that inpatient care is no longer necessary, but the physician who is responsible for the patient's hospital care does not agree. We are currently examining different methods to resolve these situations, such as a method comparable to the existing Medicare fee-for-service system. Under that system, if a hospital believes that an inpatient is ready for discharge, but cannot obtain the concurrence of the attending physician, the hospital may request PRO review of the case. We intend to discuss this issue in our forthcoming notice of proposed rulemaking.

16. Other Comments

Comment: As alluded to above, several commenters suggested that we modify the subpart M regulations to reflect the provisions of the 1997 district court order in Grijalva that was vacated by the Ninth Circuit on appeal in 1999. For example, several commenters suggested we provide for the continuation of coverage during the pendency of an expedited appeal as provided

under that district court order. Two commenters suggested that we clarify the enrollee's right to submit evidence in person. Additionally, several commenters suggested that the regulation should state that the enrollee has the right to informal, in-person communication with the reconsideration decision maker and that telephone hearings could be conducted if appropriate. One commenter opposed the implementation of the provisions in the vacated Grijalva order as too burdensome on M+C organizations.

Response: In general, we intend to implement regulatory changes that stem from the Grijalva order through upcoming notice and comment rulemaking. Thus, several of the commenters' suggestions are not addressed here. We note, however, that in some respects, we believe that the improvements to the appeals process that have been made under the M+C program already incorporate several of the provisions in the vacated Grijalva order, and in many instances are stronger. For example, the Grijalva order would have required that organization determinations be rendered within 5 working days, with the possibility of a 60-day extension. Under this regulation, we require that when an enrollee requests a service, the M+C organization must respond as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days. The M+C organization may not extend the time frame beyond an additional 14 calendar days. More significantly, unlike under

the Grijalva order, the M+C program provides an expedited 72-hour time frame for organization determinations in some cases that is shorter than the Grijalva time frame, and a similar expedited 72-hour time frame for the resolution of certain reconsiderations, while the Grijalva order provides neither. In another example illustrative of how our current M+C regulations meet or exceed the Grijalva order, at §422.586, the M+C organization is required to provide parties to the reconsideration with a "reasonable opportunity to present evidence and allegations of fact or law...in person."

Comment: One commenter urged that we eliminate the phrase in §422.574(b) which reads "and formally agrees to waive any right to payment from the enrollee for that service," because this language demeans the role of physicians as patient advocates for medically necessary services.

Response: We do not believe changes are needed in §422.574(b), which requires a physician or other provider who has furnished a service to an enrollee to formally agree to waive any right to payment from the enrollee for that service. The waiver is only required in the case of retrospective payment denials, where an enrollee has already received medically necessary services, but the noncontract physician or provider is seeking payment for furnishing those services; therefore, this phrase does not affect the role of physicians as patient advocates for

medically necessary services. In the context of receipt of payment, the role of the physician or provider is no longer as a patient advocate for medically necessary services. Therefore, the M+C regulation does not adversely affect or demean a physician's role as an advocate in prospective instances where an enrollee has not yet received health care services.

Comment: A commenter asked whether we would offer clarification of respective Medicare/Medicaid authorities, particularly with respect to New York State's existing 1115 Medicaid demonstration project. Additionally the commenter wondered if we will establish an administrative linkage between the States and the Medicare review authority for the provision of reports on reviews of adverse determinations in M+C organizations also operating as a State-defined managed long term care plan. (The commenter noted that managed long term care plans will predominantly serve the dually eligible.)

Response: We agree that access of dual eligibles to both the Medicare and Medicaid external hearing process should be clarified. The external hearing process accessed depends upon the type of services being provided. For example ,in original Medicare, enrollees who are dually eligible access Medicare services through the Medicare system. Therefore, appeals of Medicare services may be appealed through the Medicare external hearing process, if the beneficiary chooses to do so.

Medicaid-only wraparound services (such as pharmacy services) must be accessed through Medicaid. Therefore, appeals of Medicaid-only services must be appealed through the Medicaid external hearing process. Likewise in capitated managed care, when a dually eligible enrollee is enrolled in a Medicaid MCO, the capitated rates are set based on an assumption that Medicare services are accessed through the Medicare system. Therefore, the Medicaid fair hearing system is accessed only for the Medicaid capitated services. The Medicare external hearing is accessed for the Medicare services outside of the Medicaid capitation contract. If a dually eligible individual is enrolled in an M+C organization, then the Medicare external hearing is accessed for the Medicare services within the capitation contract. The enrollee accesses the Medicaid State Fair Hearing only for services outside of the Medicare contract. The key to this example is that the enrollee and the M+C organization need to know whether the service provided is a Medicare- or Medicaid-covered service.

Comment: A commenter suggested that §422.568(e), which addresses the effect of failure to provide timely notice of an organization determination, should be revised to specify that: (1) failure to give timely and proper notice shall result in an automatic authorization/approval; and/or (2) failure to give timely and proper notice shall result in automatic sanctions by

us. Furthermore, the commenter stressed that if an M+C organization fails to give proper notice, the M+C organization should be required to submit the file directly to an independent organization as described in §422.590(c). Another commenter suggested that M+C organizations that fail to comply with grievance and appeal requirements should be subject to other intermediate sanctions.

Response: If we determine that an M+C organization substantially fails to comply with the notice requirements relating to grievances and appeals in subpart M, we have the option to terminate the contract under the requirements of §422.510(b), impose intermediate sanctions as described in §§422.756(c)(1) and (c)(3), and/or impose civil money penalties as described in §422.758. We note that, depending on the seriousness of a violation (for example, in terms of the degree of risk to an enrollee's health), failure to comply with notice or appeal requirements in only one or two cases could constitute a substantial failure. Intermediate sanctions include the suspension of enrollment and marketing. We believe that these sanction requirements are most appropriately set forth in the sections of the M+C regulations dedicated to contract provisions (subpart K) and intermediate sanctions (subpart O).

We do not agree that we should add the requirement that an M+C organization's failure to give timely and proper notice shall

result in an automatic authorization/approval, or that failure to give timely and proper notice shall result in automatic sanctions. In fact, we believe the first recommendation could seriously jeopardize the enrollee's health if, for example, an enrollee requested service that could be harmful to his or her health. We note that in the case of hospital and nursing home services already being provided, we have in part implemented the commenter's suggestion, in that the M+C organization is obligated to continue to cover the services until notice of noncoverage is provided. Also, as mentioned earlier, our sanction authority includes cases where we determine an M+C organization substantially fails to comply with the requirements relating to grievances and appeals in subpart M, including the organization's failure to provide the enrollee with timely and proper notice. Finally, where an M+C organization fails to give proper notice within the time frames required for resolution, §422.590 requires the M+C organization to submit the file to the independent entity for review. We expect M+C organizations to provide enrollees with written notice for all denials (including the case of a discontinuation of a service where the enrollee disagrees (that?) the services are no longer medically necessary) according to the time frames and notice requirements set forth under subpart M and in operational instructions. However, we do not agree that it is practical, nor does the law mandate, that we require M+C

organizations to automatically forward cases for independent review when content of the notice is at issue, and there has not been an adverse organization determination (that is, a coverage denial).

Comment: A commenter suggested that M+C organizations should be required to establish an independent appeals procedure for denials of care.

Response: The M+C statute requires that we contract with an independent review entity to independently review plan denials of care. We believe that this arrangement, along with the other M+C appeal requirements, provide Medicare enrollees with the rights they need, and the rights to which they are entitled.

Comment: Two commenters did not believe that the physician reviewing the reconsideration needed to be of the same specialty or sub-specialty as the treating physician. Requiring the same specialty as the treating physician unduly complicates the reconsideration process in this commenter's view. One commenter pointed out that the BBA Conference Report states that "It is not the conferees intent to require that a physician involved in the reconsideration process in all cases be of the same specialty or sub-specialty as the treating physician." One commenter suggested that expertise should be defined in terms of board certification in the specialty, years of experience practicing in the specialty, and active practice. One commenter also suggested

that physicians have qualifications other than expertise in the field of medicine that is appropriate for the services at issue. The commenter believes that the reviewing physician should also be formally qualified in the specialty treatment (licensed and actively practicing in the same jurisdiction) as the practitioner providing (or who would provide) the services, and have the appropriate level of training and experience to judge the necessity of the service. To ensure greater professional accountability, a commenter recommended that the reviewing physician's identity be accessible to the physician who recommended, rendered, or would have rendered the treatment under review. One commenter suggested that we also include other rights found in State managed care laws, such as requiring initial (organization) determination denials to be made or approved by a physician.

Response: We agree that a physician involved in the reconsideration process need not in all cases be of the exact same specialty or sub-specialty as the treating physician; therefore, we are revising §422.590(g)(2) to make this clear. For example, we believe that there may be situations where only one specialist practices in a rural area, and therefore, it would not be possible for the M+C organization to obtain a second reviewer with expertise in the same specialty. In addition, we recognize that there may be some situations where there are few

practitioners in highly specialized fields of medicine. Under these circumstances, it would not be possible to get a physician of the same specialty or sub-specialty involved in the review of the adverse organization determination.

With respect to the commenter who specified training that the commenter believes reviewing physicians should have, we believe that our standard of "appropriate" expertise addresses this comment. Nor do we believe that it would be appropriate for the reviewing physician's identity to be provided to the treating physician being reviewed. The treating physician has the right to challenge the M+C organization's decision on the merits through several levels of an appeals process. We believe that sufficient accountability exists for reviewing physicians through the appeals process, since a physician whose decisions are reversed on appeal would be accountable to his or her M+C organization. Providing the name of the physician making the initial decision for the M+C organization could result in needless personal harassment of that physician by the physicians he or she reviews.

Finally, we do not agree with the comment that organization determinations should be made or approved by a physician. We do not believe that it is necessary to require physician involvement in all organization determinations that are adverse. Nevertheless, we expect that where adverse determinations are

based on a lack of medical necessity, M+C organizations will ensure that appropriate health care professionals will be involved in the decision-making. For example, a nurse practitioner could render an adverse organization determination without the need to involve a physician. Furthermore, if an enrollee believes that the lack of physician involvement was a central factor in an adverse organization determination, then the enrollee need only request a reconsideration since the reconsideration requirements (§422.590(g)(2)) specify that a denial of coverage based on a lack of medical necessity must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. (We note that we have made a minor technical change to §422.590(d) to clarify that the term "medical necessity" includes any substantively equivalent term used by an M+C organization to describe the concept of medical necessity.)

Comment: Several commenters provided suggestions on elements for grievance and appeal data.

Response: We appreciate the variety of comments we received concerning categories of meaningful data elements. The comments have provided valuable insight as we continue to work with the public to develop collection and reporting requirements related to organization-level appeals and grievances. Please note that OPLs 99.081 and 2000.114 provide guidance on the manner and form

in which M+C organizations will be expected to comply with the requirement under §422.111 for disclosing grievance and appeal data upon request to M+C-eligible individuals. Collection began April 1, 1999, and the first reporting went into effect on January 1, 2000.